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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/590,848 | 07/03/2007 | Roberto Pellicciari | 0113847.00127US1 | 3802 |

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WASHINGTON, DC 20004

| EXAMINER |
|---|
| BADIO, BARBARA P |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1612 | |

| NOTIFICATION DATE | DELIVERY MODE |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/590,848 | PELLICCIARI, ROBERTO | |
| | Examiner | Art Unit | |
| | Barbara P. Badio | 1612 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3,5 and 12-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 12-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Status of the Application***

2. Claims 1-3, 5 and 12-18 are pending in the present application. The instant claims are rejected as indicated below.

***Claim Rejections - 35 USC § 101***

**3. The rejection of claims 6-11 under 35 USC 101 as directed to non-statutory subject matter is made moot by the cancellation of the instant claims.**

***Double Patenting***

**4. The rejection of claims 4 and 6-11 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,138,390 is made moot by the cancellation of the instant claims.**

**5. The rejection of claims 1-3, 5 and 12 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,138,390 is maintained and claims 13-18 are rejected on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,138,390.**

Applicant argues (a) no reason was articulated as to why a person of skill in the art would have modified the compounds recited by the '390 patent and (b) the 7 position in biliary acid compounds provide for significant differences and reference is made to the differences in the amount UDCA and CDCA in human bile pool and the teaching by Pellicciari that UDCA is not a ligand for FXR. Applicant's argument was considered but not persuasive for the following reasons.

First, as indicated in the previous Office Action, (a) the claimed compound is the 7β-isomer of the compound of '390 and (b) both CDCA and UDCA are known in the art. Based on the knowledge in the art of the uses of biliary acid compounds, the corresponding 7β-isomer of the compound of '390 would be obvious. Also, as indicated in the previous Office Action, in the absence of unobvious and/or unexpected beneficial properties, an isomer of a known compound is unpatentable. Thus, reasons were articulated as to why the claimed compound would have been obvious to one of skill in the art.

Applicant also argues the differences in the amount of UDCA and CDCA in human bile pool and the teaching by Pellicciari that UDCA, unlike CDCA, is not a ligand for FXR. It is noted that there is no requirement that the prior art must suggest similar property/use as discovered by applicant in order to support a legal conclusion of obviousness.

The prior art is saturated with teachings of the use of both UDCA and CDCA in the treatment of similar conditions such as biliary calculosis (see for example, US patent

Nos. 4,931,038; 4,264,583; 4,460,309). Therefore, the 7β-isomer of the cited patent would have been obvious based on the knowledge of UDCA and CDCA in the art.

For these reasons and those given in the previous Office Action, the rejection of claims 1-3, 5 and 12 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,138,390 is maintained and claims 13-18 are rejected on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,138,390.

**6. The provisional rejections of claims 4 and 6-11 on the ground of nonstatutory obviousness-type double patenting over claims of copending Application Nos. (a) 11/081,002, (b) 11/602,307 and (c) 11/914,559 are made moot by the cancellation of the instant claims.**

**7. The provisional rejections of claims 1-3, 5 and 12 on the ground of nonstatutory obviousness-type double patenting over claims of copending Application Nos. (a) 11/081,002, (b) 11/602,307 and (c) 11/914,559 are maintained and claims 13-18 are provisionally rejected on ground of nonstatutory obviousness-type double patenting over claims of copending Application Nos. (a) 11/081,002, (b) 11/602,307 and (c) 11/914,559.**

Applicant's statement that the provisional rejections be held in abeyance is noted.

**8. The provisional rejections of claims 4 and 6-11 on the ground of nonstatutory obviousness-type double patenting over claims of copending Application No. 11/842,002 is made moot by the cancellation of the instant claims.**

**9. The provisional rejections of claims 1-3, 5 and 12 on the ground of nonstatutory obviousness-type double patenting over claims of copending Application No. 11/842,002 is withdrawn.**

The abandonment of the cited copending Application is noted.

***Claim Rejections - 35 USC § 112***

**10. The rejection of claims 6-8 and 11 under 35 USC 112, first paragraph, scope of enablement is made moot by the cancellation of the instant claims.**

**11. The rejection of claims 6, 7 and 11 under 35 USC 112, first paragraph, enablement is made moot by the cancellation of the instant claims.**

**12. The rejection of claims 6, 7 and 11 under 35 USC 112, first paragraph, written description is made moot by the cancellation of the instant claims.**

**13. The rejection of claims 6, 7 and 11 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claims.**

**14. The rejection of claim 3 under 35 USC 112, second paragraph is withdrawn.**

***Claim Rejections - 35 USC § 103***

**15. The rejection of claims 4 and 6-11 under 35 USC 103(a) over Frigerio et al. (EP 312,867) is made moot by the cancellation of the instant claims.**

**16. The rejection of claims 1-3, 5 and 12 under 35 USC 103(a) over Frigerio et al. (EP 312,867) is maintained and claims 13-18 are rejected under 35 USC 103(a) over Frigerio et al. (EP 312,867).**

Applicant argues the reference teaches methyl at the C-6 position was to introduce steric hindrance to the molecule and was not seeking to produce a potent FXR agonist since FXR receptors were not discovered until 1999. Applicant's argument was considered but not persuasive for the following reasons.

There is no requirement that the prior art must suggest that the claimed compounds have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. *In re Dillon*, 919 F.2d 688, 696, USPQ 2d 1897, 1904 (Fed. Cir. 1990). An obviousness rejection is proper as long as the prior art suggests a reason or provides motivation to make the claimed invention, even where the reason or motivation differs from that discovered by applicant. As the Dillon opinion notes, applicant has the burden and opportunity to present relevant evidence to overcome the rejection. Applicant has not provided any evidence that the claimed compound would not have been obvious based on the prior art.

As stated in the previous Office Action, the instant compound is obvious because (a) the prior art teaches the adjacent lower homolog and, thus, the skilled artisan would have the reasonable expectation that compounds differing only in a single $-CH_2-$ would have similar properties and (b) the court has held that adjacent homologs are obvious absence a showing of unexpected and/or unobvious results.

For these reasons and those given in the previous Office Action, the rejection of claims 1-3, 5 and 12 under 35 USC 103(a) over Frigerio et al. (EP 312,867) is maintained and claims 13-18 are rejected under 35 USC 103(a) over Frigerio et al. (EP 312,867).

## ***Conclusion***

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiry***

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1612